

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
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THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 9165

Bartle, J.

November 10, 2013

Beverly A. Ellis ("Ms. Ellis" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation. In 2009, Pfizer, Inc. acquired Wyeth.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2010, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Paul W. Dlabal, M.D., F.A.C.P., F.A.C.C., F.A.H.A. Based on an echocardiogram dated April 22, 2002,<sup>3</sup> Dr. Dlabal attested in Part II of claimant's Green Form that Ms. Ellis suffered from moderate aortic regurgitation and had surgery to repair or replace the aortic and/or mitral valve(s) following the use of

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2. (...continued)

serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Claimant's Green Form relies on an echocardiogram dated April 22, 2002. The Show Cause Record, however, contains an echocardiogram report dated April 20, 2002. The parties do not dispute that the echocardiogram report dated April 20, 2002 is the report of claimant's April 22, 2002 echocardiogram.

Pondimin® and/or Redux™.<sup>4</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$335,553.<sup>5</sup>

In the report of claimant's echocardiogram, the reviewing cardiologist, B. Shields Stutts, M.D., F.A.C.C. stated, "There is calcific aortic stenosis, which is mild to moderate." Dr. Stutts measured claimant's aortic valve area to be 1.39 cm<sup>2</sup>. Dr. Dlabal attested in claimant's Green Form that Ms. Ellis did not suffer from aortic stenosis.<sup>6</sup> Under the Settlement Agreement, the presence of "[a]ortic stenosis with an aortic valve area < 1.0 square centimeter by the Continuity Equation" requires the payment of reduced Matrix Benefits. Settlement Agreement § IV.B.2.d.(2)(c)i)e). As the Trust does not contest claimant's entitlement to Level III benefits, the only issue

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4. Dr. Dlabal also attested that claimant suffered from mild mitral regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class III symptoms. These conditions are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level III benefits if he or she suffers from "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a).

6. In addition, Dr. Dlabal attested that claimant did not suffer from aortic sclerosis. The Trust disputes this representation. Under the Settlement Agreement, the presence of aortic sclerosis in claimants who were sixty (60) years of age or older at the time they were first diagnosed as FDA Positive also requires the payment of reduced Matrix Benefits. See id. § IV.B.2.d.(2)(c)i)c). Given our disposition with respect to whether claimant has aortic stenosis, we need not determine this dispute.

before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In December, 2010, the Trust forwarded the claim for review by Robert L. Gillespie, M.D., F.A.C.C., F.A.S.E., one of its auditing cardiologists. In audit, Dr. Gillespie concluded that there was no reasonable medical basis for Dr. Dlabal's finding that claimant did not have aortic stenosis with an aortic valve area less than 1.0 square centimeter by the Continuity Equation. In support of this conclusion, Dr. Gillespie stated, "The aortic valve on 4/22/02 had mild [aortic stenosis] and the subsequent studies on 8/28/09 and 9/4/09 had severe [aortic stenosis]. The [aortic valve area] was not less than 1 cm<sup>2</sup> on the first [echocardiogram] but was on the 2 subsequent studies."

Based on Dr. Gillespie's finding, the Trust issued a post-audit determination that Ms. Ellis was entitled only to Matrix B-1, Level III benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>7</sup> In contest, claimant argued that there was a reasonable medical basis for Dr. Dlabal's representation that Ms. Ellis had aortic stenosis because the aortic stenosis on her April 22, 2002 echocardiogram was

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

"insufficient to reduce the claim." According to Ms. Ellis, the Trust is not permitted to rely upon more recent echocardiograms in determining whether to apply a reduction factor because the Settlement Agreement requires that the requisite level of aortic stenosis be present on the echocardiogram that forms the basis for her claim, here, claimant's April 22, 2002 echocardiogram.<sup>8</sup>

Although not required to do so, the Trust forwarded the claim for a second review by the auditing cardiologist. Dr. Gillespie submitted a declaration in which he again concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Ellis did not have aortic stenosis as defined by the Settlement Agreement. Dr. Gillespie stated, in relevant part:

As I stated at audit, Claimant had mild to moderate aortic stenosis at the time of the 4/22/02 echocardiogram. At that time the aortic valve was stenotic, but the [aortic valve area] was not less than 1cm<sup>2</sup>. However, the studies dated 8/28/09 and 9/4/09, performed shortly before Claimant's 9/15/09 aortic valve surgery, show severe aortic stenosis with an aortic valve area less than 1cm<sup>2</sup>. Therefore, based upon all of the medical records available for review, there is no reasonable medical basis to conclude that Claimant did not have aortic stenosis with an [aortic valve area] less than 1cm<sup>2</sup>.

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8. Claimant also requested any instructions or directives given to the auditing cardiologist by the Trust because she contends the auditing cardiologist was not independent as required by the Settlement Agreement. As there is no evidence the auditing cardiologist did not perform an independent review of this claim, we reject this argument.

The Trust then issued a final post-audit determination, again determining that Ms. Ellis was entitled only to Matrix B-1, Level III benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On August 16, 2011, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 8666 (Aug. 16, 2011).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 11, 2012, and claimant submitted a sur-reply on February 7, 2012. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>9</sup> to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare

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9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge--helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where conflicting expert opinions exist, it is within the discretion of the court to appoint a Technical Advisor to aid it in resolving technical issues. Id.

a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden of proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Ellis did not have aortic stenosis with an aortic valve area  $< 1.0$  square centimeter by the Continuity Equation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Ellis reasserts the arguments made in contest. In addition, claimant contends that the Settlement Agreement and other related documents provide that the Trust's review is limited only to one echocardiogram. Finally, Ms. Ellis argues that while Dr. Gillespie stated that her echocardiograms dated August 28, 2009 and September 4, 2009 reveal aortic stenosis with an aortic valve area less than 1.0 square centimeter, he did not state that this determination was made by using the Continuity Equation as required by the Settlement Agreement.

In response, the Trust counters that claimant did not establish a reasonable medical basis for Dr. Dlabal's representations that claimant did not have aortic stenosis as defined by the Settlement Agreement. In addition, the Trust asserts that there is no temporal limitation for finding the presence of the reduction factors of aortic stenosis or aortic sclerosis.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiograms and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant did not have aortic stenosis. Specifically, Dr. Vigilante explained:

The CD of the transthoracic echocardiogram on September 4, 2009 was reviewed.... Pulse wave and continuous wave dopplers in the left ventricular outflow tract and through the aortic valve were reviewed. The LVOT was 1.8 cm in diameter. Therefore, the left ventricular outflow tract area was 2.54 cm<sup>2</sup>. The mean velocity in the left ventricular outflow tract was 0.50 meters per second. The mean velocity through the aortic valve was 3.56 meters per second. Therefore, the aortic valve area calculated via the Continuity Equation was 0.36 cm<sup>2</sup>.

....

... [T]here is no reasonable medical basis for the Attesting Physician's answer to Green Form Question D.5. That is, the Claimant had obvious aortic stenosis with an aortic valve area significantly less than 1.0 cm<sup>2</sup> by the Continuity Equation on the echocardiographic study of September 4, 2009. An echocardiographer could not reasonably conclude that this study did not show aortic stenosis with an aortic valve area of less



than 1.0 cm<sup>2</sup> by the Continuity Equation even taking into account inter-reader variability.

In response to the Technical Advisor Report, Ms. Ellis argues that she is entitled to Matrix A-1 benefits because the Technical Advisor did not find an aortic valve area less than 1.0 square centimeter by the Continuity Equation using claimant's April 22, 2002 echocardiogram.<sup>10</sup>

After reviewing the entire Show Cause Record, we find that claimant has failed to meet her burden of demonstrating that she is entitled to Matrix A-1 benefits. The Settlement Agreement requires that a claim for benefits based on damage to the aortic valve be reduced to Matrix B-1 if claimant had aortic stenosis with an aortic valve area less than 1.0 square centimeter by the Continuity Equation. See Settlement Agreement § IV.B.2.d.(2)(c)i)e). Here, the Technical Advisor and the

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10. Claimant initially included with her response to the Technical Advisor Report a supplemental declaration by Dr. Dlabal. Pursuant to Audit Rule 34, the Special Master advised Ms. Ellis that Dr. Dlabal's supplemental declaration could not become part of the Show Cause Record. Thereafter, claimant filed "objections" to the decision denying the inclusion of Dr. Dlabal's supplemental declaration in the Show Cause Record. According to claimant, in his supplemental declaration, Dr. Dlabal disputed the Technical Advisor's finding of aortic sclerosis on claimant's April 22, 2002 echocardiogram. Pursuant to Audit Rule 34, there is no procedure by which Dr. Dlabal's supplemental declaration can become part of the Show Cause Record. See Mem. in Supp. of PTO No. 9041, at 9 n.11 (Apr. 5, 2013); Mem. in Supp. of PTO No. 8402, at 12 n.13 (Feb. 22, 2010). In any event, the supplemental declaration of Dr. Dlabal is irrelevant to the resolution of Ms. Ellis's claim because his substantive challenges concern only the issue of aortic sclerosis. For all of these reasons, we will overrule claimant's objections.

auditing cardiologist found that claimant's aortic valve area was less than 1.0 square centimeter using her September 4, 2009 echocardiogram. Specifically, Dr. Vigilante found that "the aortic valve area calculated via the Continuity Equation was 0.36 cm<sup>2</sup>." Dr. Gillespie also found that claimant's aortic valve area on her September 4, 2009 echocardiogram was "less than 1 cm<sup>2</sup>."

Significantly, none of claimant's physicians disputes that her September 4, 2009 echocardiogram shows the presence of aortic stenosis with an aortic valve area less than 1.0 square centimeter by the Continuity Equation. Instead, Ms. Ellis argues that this later echocardiogram should be disregarded because, according to claimant, the reduction factors set forth in the Settlement Agreement, such as aortic stenosis, have a temporal limitation. We recently rejected this argument, holding that "[t]o avoid receiving reduced Matrix Benefits, claimant must demonstrate, at a minimum, that she did not suffer from a reduction factor at the time she suffered from the conditions supporting her supplemental claim." See Mem. in Supp. of PTO No. 8822, at 9 (Feb. 22, 2012), aff'd, In re: Diet Drugs (Phentermine/Fenfluramine/Dexfenfluramine) Prods. Liab. Litig., No. 12-3138, 2013 WL 2166119 (3d Cir. Oct. 9, 2012); see also Mem. in Supp. of PTO No. 8743, at 2-7 (Dec. 27, 2011). As claimant does not dispute the presence of aortic stenosis as defined by the Settlement Agreement on her September 4, 2009 echocardiogram, which was performed prior to September 15, 2009,

the date of her aortic valve surgery, the Settlement Agreement requires that her Level III claim be reduced to Matrix B-1.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have aortic stenosis with an aortic valve area less than 1.0 square centimeter by the Continuity Equation. Therefore, we will affirm the Trust's denial of the claim of Ms. Ellis for Matrix A, Level III benefits.